

**Notice of Allowability**

Application No.

10/768,193

Applicant(s)

YANAGISAWA ET AL.

Examiner

Kimberly A. Ballard

Art Unit

1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the supplemental response filed 07 September 2007 and the interview of 28 September 2007.

2. ☒ The allowed claim(s) is/are 3-7, 32 and 33.

3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some\* c) ☐ None of the:

1. ☒ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.

(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached

1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.

(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of

Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)

2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3. ☐ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_

4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material

5. ☐ Notice of Informal Patent Application

6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_

7. ☒ Examiner's Amendment/Comment

8. ☒ Examiner's Statement of Reasons for Allowance

9. ☐ Other \_\_\_\_\_.

### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Jamie Armstrong on September 28, 2007.

The application has been amended as follows:

#### IN THE CLAIMS:

3. A recombinant antibody or antigen-binding fragment thereof having specificity for having an activity of recognizing GM1 ganglioside-bound amyloid  $\beta$ -protein and which inhibits ~~inhibiting the formation of amyloid fibrils, the antibody being IgG or Fab,~~ comprising: a heavy chain variable region, and a light chain variable region; wherein the heavy chain variable region comprises complementarity ~~complementary~~ determining regions (CDRs) described in g), h) and i), and the light chain variable region comprises CDRs described in j), k) and l);

g) CDR 1 consisting of the ~~an~~-amino acid sequence of SEQ ID NO. 1;

h) CDR 2 consisting of the ~~an~~-amino acid sequence of SEQ ID NO. 2;

i) CDR 3 consisting of the ~~an~~-amino acid sequence of SEQ ID NO. 3;

j) CDR 1 consisting of the ~~an~~-amino acid sequence of SEQ ID NO. 4;

k) CDR 2 consisting of the ~~an~~-amino acid sequence of SEQ ID NO. 5; and

Art Unit: 1649

l) CDR 3 consisting of the ~~an~~-amino acid sequence of SEQ ID NO. 6.

4. The antibody or antigen-binding fragment thereof according to claim 3, wherein the heavy chain variable region comprises the ~~an~~-amino acid sequence of SEQ ID NO: 7.

5. The antibody or antigen-binding fragment thereof according to claim 3, wherein the light chain variable region comprises the ~~an~~-amino acid sequence of SEQ ID NO: 8.

6. The antibody or antigen-binding fragment thereof according to claim 3, wherein the heavy chain variable region comprises the ~~an~~ amino acid sequence of SEQ ID NO: 7; and the light chain variable region comprises the ~~an~~ amino acid sequence of SEQ ID NO: 8.

7. The antibody or antigen-binding fragment thereof according to claim 3, which is a humanized antibody.

32. The antibody or antigen-binding fragment thereof according to claim 3, wherein the antibody is isotype IgG1, IgG2, IgG3 or IgG4.

Art Unit: 1649

33. The antibody or antigen-binding fragment thereof according to claim 3, wherein the antigen-binding fragment is Fab, Fab', F(ab')<sub>2</sub>, scFv or dsFv.

***Reasons for Allowance***

The following is an examiner's statement of reasons for allowance:

The declaration under 37 CFR 1.132 filed May 22, 2007 is sufficient to overcome the rejections of claims 3-7 based upon the Yanagisawa et al. (1997) reference applied under 35 U.S.C. 103.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly A. Ballard whose telephone number is 571-272-4479. The examiner can normally be reached on Monday-Friday 9AM - 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kimberly Ballard, Ph.D.  
September 28, 2007

/Elizabeth C. Kemmerer/  
Primary Examiner, Art Unit 1646